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(54) Intravascular stent and stent delivery system for ostial vessel obstructions

(57) Disclosed is a stent and stent delivery system specifically designed for implantation of a stent at the ostium of a vessel. Such a system is specifically designed to be able to create and maintain patency of lesions such as renal artery ostial stenoses or bypass graft ostial stenoses. The stent portion of this system has an increased distal flexibility before expansion and an increased proximal radial rigidity after expansion. In addition, this stent may also have its most proximal struts able to be flared out so as not to "hang out" into a major artery such as the aorta. This stent can be combined with a specially designed stent delivery catheter which has a balloon with a tapered shape to allow increased expansion of the proximal section of the stent. This balloon can also produce flaring out of the most proximal stent struts.

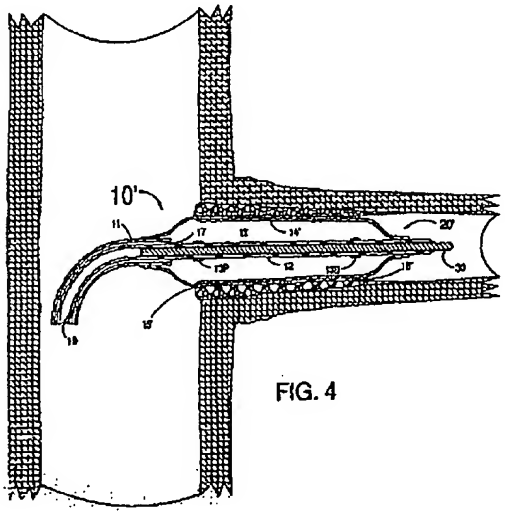

FIG. 4

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Description

This invention is in the field of intravascular stents that are used to maintain patency of a blood vessel.

BACKGROUND OF THE INVENTION

It has been shown that intravascular stents are an excellent means to maintain the patency of blood vessels following balloon angioplasty. Robert and Tim Fischell in U.S. Pat. No. 4,768,507 describe a helical spring stent design. Palmaz in U.S. Pat. No. 4,733,665 describes a balloon expandable slotted tube stent. Both these designs and others currently known in the art would have fairly uniform stent flexibility before deployment and a reduced radial strength at the proximal and distal ends of the stent after deployment.

Ostial obstructions such as those that often occur at the junction of the aorta and renal artery are difficult to treat with standard angioplasty balloons or stents. Ostial lesions tend to exhibit extreme elastic recoil which makes balloon angioplasty ineffective. Typical stent designs (such as the Palmaz type) have minimal radial strength near each end when deployed. If the stent is allowed to protrude into the aorta so that a more rigid section can engage the ostial lesion, then complications such as stent thrombosis can occur from the bare metal extending out into the blood stream. In addition, the stent mounted on the delivery catheter must often make an almost 90 degree bend to enter the renal artery from the aorta. The longitudinal stiffness of the Palmaz type stent can make this maneuver difficult.

SUMMARY OF THE INVENTION

This invention describes a stent and stent delivery system specifically designed for implantation of a stent at the ostium of a vessel. It is also specifically designed to be able to maintain the patency of lesions such as renal artery ostial obstructions or the ostium of bypass grafts where they are attached to the aorta.

The present invention is a specially designed stent with an increased proximal radial rigidity after expansion and an increased distal flexibility before expansion. In addition this stent may also have the most proximal struts able to be flared out so as not to "hang out" into the aorta This stent can be combined with a specially designed stent delivery catheter which has a balloon with a tapered shape to allow increased expansion of the proximal section of the stent. This balloon can also produce flaring out of the most proximal stent struts. In addition the combination of radiopaque markers and/or a self-expanding proximal strut attached to a balloon expandable stent could facilitate accurate placement of an ostial stent.

Thus it is an object of this invention to have a deployed stent with its proximal section having greater rigidity than the remainder of the stent.

Another object of this invention is to have a non-deployed stent with a distal section having more longitudinal flexibility than the remainder of the stent.

Still another object of this invention is to have the most proximal stent struts capable of being flared out to avoid having metal extend proximal into the vessel's ostium.

Still another object of this invention is to have the stent delivery catheter have a balloon which expands to a larger diameter at its proximal end.

Still another object of this invention is to have the stent delivery catheter have a balloon for stent delivery which is specially designed to flare out the stent's proximal end struts.

Still another object of this invention is to have a stent with radiopaque markers located on the most proximal struts.

These and other objects and advantages of this invention will become obvious to a person of ordinary skill in this art upon reading of the detailed description of this invention including the associated drawings as presented herein.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a longitudinal cross section of an ostial stent and stent delivery catheter with the delivery balloon expanded.

FIG. 2 is a transverse cross section at 2 - 2 from FIG. 1 for an ostial stent and stent delivery catheter with the delivery balloon expanded.

FIG. 3 is a longitudinal cross section of an ostial stent and stent delivery catheter in place at the ostium of a blood vessel just before deployment of the ostial stent..

FIG. 4 is a longitudinal cross section of an ostial stent and stent delivery catheter in place at the ostium of a blood vessel with the balloon expanded for deployment of the ostial stent.

FIG. 5 is a longitudinal cross section showing the ostial stent in place at the ostium of a blood vessel after the ostial stent has been deployed, the balloon has been deflated and the stent delivery catheter has been removed from the body.

FIG. 6 is a flat lay out view of an ostial stent design in its non-deployed state.

FIG. 7 is a flat lay out view of a structural strut member of the ostial stent shown in FIG. 6.

FIG. 8 is a flat lay out view of an ostial stent design in its deployed state.

DETAILED DESCRIPTION OF THE DRAWINGS

FIG. 1 is a longitudinal cross section of an ostial stent delivery system 10' comprising an ostial stent 16' and a stent delivery catheter 20' having a delivery balloon which is 14' expanded to deploy the stent 16',

The stent delivery catheter 20' consists of an inner

shaft 12, an outer shaft 11, an inflatable balloon 14' that is attached at its proximal end to the outer shaft 11 and at its distal end to the inner shaft 12. An annular passageway 17 that lies between the outer surface of the inner shaft 12 and the inner surface of the outer shaft 11 is in fluid communication with the annular space 18' within the balloon 14', thus allowing inflation and deflation of the balloon 14'. The inner shaft 12 has a central lumen 19 through which to guide wire 30 can be slideably moved. When inflated, the balloon 14' is tapered with a larger diameter at its proximal end compared to its distal end. A bulge 21' near the proximal end of the expanded balloon 14' provides additional expansion to further expand the most proximal strut 15' of the stent 16' to insure that the proximal strut 15' is fully embedded in the arterial wall at the ostium of the implanted vessel as is seen in FIGS. 4 and 5. The bulge 21' may be made of a non-compliant balloon material where there is little change in bulge diameter with balloon inflation pressure or it may be made from a compliant material where it will increase in diameter with inflation pressure to allow for further increases in expansion of the proximal strut 15'. The balloon 14' may be made of a non-compliant plastic which is preformed in the shape shown in FIG. 1 and then folded down over the inner catheter shaft 12. It could also be made of a compliant plastic whose thickness tapers from its thickest at the distal end to its thinnest at the proximal end. For this design, as inflation pressure increases the balloon 14' will expand to a greater diameter at its proximal end than its distal end. What is more, the slope of the taper will increase with higher pressure.

The stent delivery catheter 20' has a proximal radiopaque marker band 13P and a distal radiopaque marker band 13D which generally indicate the proximal and distal extremities of the stent 16' after the balloon 14' is inflated to deploy the stent 16'. It should be noted that in FIG. 1 the wires of the stent 16' are doser together for the proximal section to provide greater radial strength, and are farther apart at the distal section to allow for greater flexibility.

FIG. 2 is a transverse cross section at 2 - 2 from FIG. 1 for the ostial stent delivery system 10' showing the expanded balloon 14' and expanded ostial stent 16'.

FIG. 3 is a longitudinal cross section of an ostial stent delivery system 10 with stent delivery catheter 20 and non-deployed ostial stent 16 in place over the guide wire 30 at the ostium of a blood vessel just prior to deployment of the ostial stent 16 by inflation of the balloon 14.

FIG. 4 is a longitudinal cross section of the ostial stent delivery system 10' with stent delivery catheter 20' and ostial stent 16', in place over the guide wire 30 at the ostium of a blood vessel after deployment of the ostial stent 16' by inflation of the balloon 14'. Following this step, the balloon 14' is deflated and the stent delivery catheter 20 and guide wire 30 are removed from the body leaving the ostial stent 16', in place at the ostium of the blood vessel as is shown in FIG. 5. It is important to note that the proximal strut 15' of the expanded stent 16' is expanded to a greater diameter than the rest of the stent 16' so as to reduce the probability ofthe proximal strut 15' extending proximally into the aorta.

FIG. 5 is a longitudinal cross section showing the ostial stent 16' in place at the ostium of a blood vessel after the ostial stent 16' has been deployed, the balloon 14' has been deflated and the stent delivery catheter 20 and guide wire 30 have been removed from the body.

FIG. 6 is a flat lay out view of an ostial stent 16 in its pre-deployment state. The ostial stent 16 is typically laser cut from a stainless steel tube with sets of strut members 40 comprising diagonal struts members 25 with curved ends 29 joined by the circumferential sections 23, shown in an enlarged view in FIG. 7. The sets of strut members 40 are the part of the stent 16 which unfold during expansion and provide the radially rigid structure which maintains vessel patency.

The stent 16 has many sets of strut members 40 which are connected to each other with sets of either longitudinal "H" cross bars 22 or longitudinal "S" undulations 24. The "H" cross bars 22 are shorter in the longitudinal direction than the "S" undulations 24. When the "H" cross bars 22 are used as interconnections, the connected sets of strut members 40 will be closer and more rigidly connected to each other and the radial strength of that section of expanded stent will be increased at the expense of longitudinal flexibility. When the "S" undulations interconnect the sets of strut members 40, the longitudinal flexibility of that section of stent will be increased. The ostial stent 16 of FIG. 6 has a proximal section 26 and distal section 28. The proximal section 26 is composed adjacent sets of strut members 40 having only "H" interconnections 22 to maximize the expanded radial strength. The distal section 28 is composed of adjacent sets of strut members 40 interconnected with only "S" undulations 24 to maximize the longitudinal flexibility. An alternate embodiment (not shown) might have the most distal set of strut members interconnected with "H" cross bars so as to assist the normally radially weak end of the stent. The most proximal strut 15 with radiopaque markers 31 can be given additional expansion during stent deployment as shown in FIGS. 1, 4 and 5.

FIG. 8 is a flat lay out view of the ostial stent 16' in its deployed state having deployed diagonal struts 25'. It should be noted here that, in the expanded state, the sets of strut members 40 are closer together and more rigidly connected with the "H" cross bars 22 in the proximal section 26 while the "S" undulations 24 do not as rigidly connect the sets of strut members 40 which are more widely spaced in the distal section 28 of the ostial stent 16'. This design increases the rigidity of the deployed proximal section 26 of the ostial stent 16 while increasing the non-deployed flexibility of the distal section 28.

Although "S" shaped undulations 24 are shown

here, it is also envisioned that either one half of an "S" (a "U") or "S" and "U" undulations connected together or in any combination could also enhance the flexibility of the distal section 28 of the present invention.

Although FIGS. 1 through 4 inclusive illustrate "over-the-wire" types of catheters for delivering a balloon expandable stent, it should be understood that this invention of an ostial stent delivery system could also be used with a "rapid exchange" type of the stent delivery catheter in which the guide wire would exit from the stent delivery catheter near its distal end proximal to the stent location. It is also envisioned that a tubular sheath positioned over the stent and stent delivery catheter could be used in conjunction with this ostial stent 16 and tapered balloon delivery catheter 20. It is also envisioned that an ostial self-expanding stent made of a material such as Nitinol could be produced and heat treated in the shape shown in FIG. 8 then cooled and folded down to the shape in FIG. 6 for introduction into the human body.

The materials of the stent delivery catheter system 10 are well known in the art of devices for interventional cardiology. Typically, all elastomer parts could be made from elastomers such as polyurethane, polyethylene, PTFE, FEP, or any similar plastic. The ostial stent 16 is ideally laser machined from a tube of metal such as stainless steel or tantalum.

Another means to increase the relative radial strength of the proximal end of the stent is to increase the strut width of the bend 29 of the diagonal struts 25. It is also envisioned that having a stent machined from a tube having an increased wall thickness at the proximal end would provide a stent with a greater radial rigidity at its proximal end. Still further it is possible that annealing the distal half of a stent to soften the metal would increase the flexibility of the distal section.

Various other modifications, adaptations, and alternative designs are of course possible in light of the above teachings. Therefore, it should be understood at this time that within the scope of the appended claims the invention may be practiced otherwise than as specifically described herein.

Claims

1. A stent delivery catheter system for placing a stent within a vessel of a human body, the system comprising:

   (a) a flexible guide wire extending in a longitudinal direction;
   (b) a stent delivery catheter having a distal section and a proximal section, said stent delivery catheter having a longitudinally directed central lumen for slideable insertion therethrough of said flexible guidewire, said distal section of said stent delivery catheter including a deployable stent mounted on an expandable balloon having a distal section and a proximal section, said proximal section of said balloon adapted to be expanded to a larger diameter than the diameter of said distal section of said balloon upon inflation of said balloon.

2. The stent delivery catheter system as recited in claim 1 where said proximal section of said balloon is formed of a non-compliant material.

3. The stent delivery catheter system as recited in claim 1 where said proximal section of said balloon is formed of compliant material.

4. The stent delivery catheter system as recited in claim 1 where the proximal end of said balloon proximal section includes a bulged section having a larger diameter than said after expansion of said balloon as compared with the remainder of said proximal section of said balloon.

5. A stent for maintaining the patency of a vessel of the human body comprising a multiplicity of sets of strut members, adjacent sets of strut members coupled each to the other in a longitudinal extension forming a one piece stent construction, said stent having a proximal section and a distal section, said proximal section having a greater radial rigidity following deployment than said distal section.

6. The stent as recited in claim 5 where said proximal section of said stent has a greater number of sets of strut members per unit length than the distal section.

7. The stent as recited in claim 5 where said sets of strut members of said proximal section have an average dimensional wall thickness greater than an average dimensional wall thickness of said of sets of strut members of said distal section stent.

8. The stent as recited in claim 5 where said sets of strut members of said proximal section have an average dimensional strut width greater than an average dimensional strut width of said sets of strut members of said distal section of said stent.

9. The stent recited in claim 5 including a plurality of substantially linearly directed "H" cross bars connecting adjacent sets of strut members in said proximal section of said stent.

10. The stent as recited in claim 5 where said stent is radially expanded responsive to inflation of a balloon onto which balloon the stent is mounted.

11. The stent as recited in claim 5 where said stent is a

radially self-expanding stent.

12. The stent of claim 5 including at least one radiopaque marker formed on a proximal strut member of the most proximal set of strut members.

13. A stent for maintaining the patency of a vessel of the human body comprising a multiplicity of sets of strut members, adjacent sets of strut members coupled each to the other in a longitudinal extension forming a one piece stent construction, said stent having a proximal section and a distal section, said distal section of said stent having a greater longitudinal flexibility prior to deployment when taken with respect to the longitudinal flexibility of said proximal section of said stent.

14. The stent as recited by claim 13 where at least two adjacent located sets of said strut members are coupled each to the other by at least two substantially longitudinally extending undulating members.

15. The stent as recited by claim 14 where the substantially longitudinally extending undulating members are formed in an S-shaped contour.

16. The stent as recited by claim 14 where the substantially longitudinally extending undulating members are formed in a U-shaped contour.

17. The stent of claim 13 including at least one radiopaque marker formed on a proximal strut member of the most proximal set of strut members.

18. The stent as recited in claim 13 where said stent is radially expanded responsive to inflation of a balloon onto which balloon the stent is mounted.

19. The stent as recited in claim 13 where said stent is a radially self-expanding stent.

20. The stent as recited in claim 13 where said sets of strut members of said distal section have an average dimensional wall thickness smaller than an average dimensional wall thickness of said of sets of strut members of said proximal section stent.

21. The stent as recited in claim 13 where said sets of strut members of said distal section have an average dimensional strut width less than the average dimensional strut width of said sets of strut members of said proximal section of said stent.

22. A stent delivery catheter system for placing a stent within a vessel of a human body, the system comprising:

(a) a flexible guide wire extending in a longitudinal direction;

(b) a stent delivery catheter having a distal section and a proximal section, said stent delivery catheter having a longitudinally directed central lumen for slideable insertion therethrough of said flexible guidewire, said distal section of said stent delivery catheter including a deployable stent mounted on an expandable balloon having a distal section and a proximal section, said proximal section of said balloon adapted to be expanded to a larger diameter than the diameter of said distal section of said balloon upon inflation of said balloon;

(c) a deployed stent for maintaining the patency of a vessel of the human body comprising a multiplicity of sets of strut members, adjacent sets of strut members coupled each to the other in a longitudinal extension forming a one piece stent construction, said deployed stent having a proximal section and a distal section, said proximal section having a greater radial rigidity than said distal section of said deployed stent.

23. The stent delivery system as recited in claim 22 where said proximal section of said stent has a greater number of sets of strut members per unit length than the distal section.

24. A stent delivery catheter system for placing a stent within a vessel of a human body, the system comprising:

(a) a flexible guide wire extending in a longitudinal direction;

(b) a stent delivery catheter having a distal section and a proximal section, said stent delivery catheter having a longitudinally directed central lumen for slideable insertion therethrough of said flexible guidewire, said distal section of said stent delivery catheter including a deployable stent mounted on an expandable balloon having a distal section and a proximal section, said proximal section of said balloon adapted to be expanded to a larger diameter than the diameter of said distal section of said balloon upon inflation of said balloon;

(c) a non-deployed stent for maintaining the patency of a vessel of the human body comprising a multiplicity of sets of strut members, adjacent sets of strut members coupled each to the other in a longitudinal extension forming a one piece stent construction, said stent having a proximal section and a distal section, said distal section of said non-deployed stent having a greater longitudinal flexibility when taken with respect to the longitudinal flexibility of said proximal

section of said non-deployed stent.

25. The stent delivery catheter system as recited by claim 24 where the stent has at least two adjacent located sets of said strut members coupled each to the other by at least two substantially longitudinally extending undulating members.

26. The stent delivery catheter system as recited by claim 24 where the stent's substantially longitudinally extending undulating members are formed in an S-shaped contour.

27. The stent delivery catheter system as recited by claim 24 where the stent's substantially longitudinally extending undulating members are formed in an U-shaped contour.

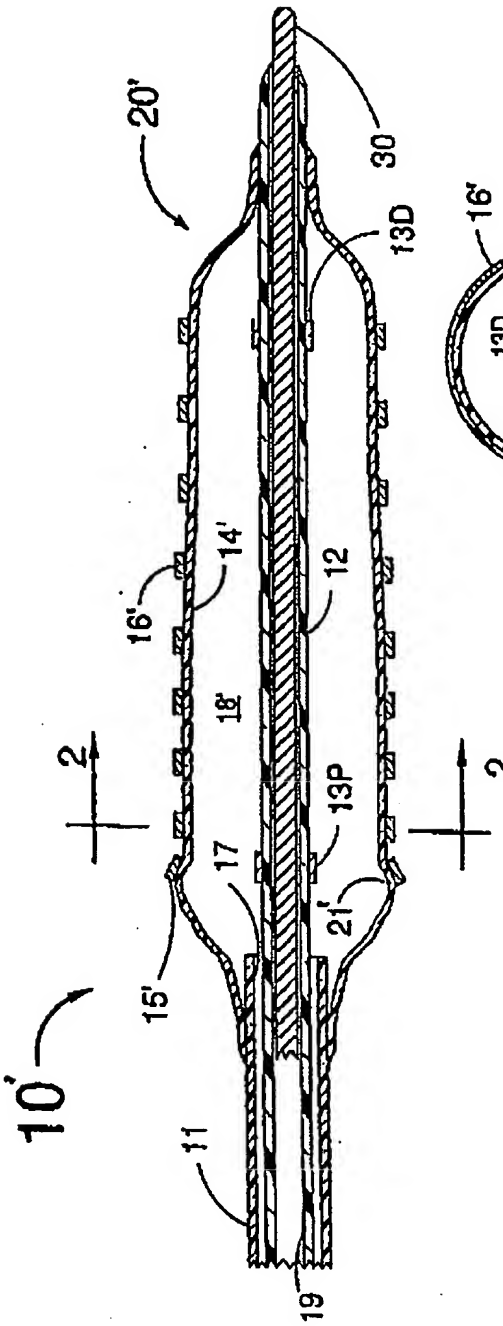

FIG. 1

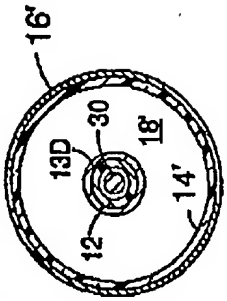

FIG. 2

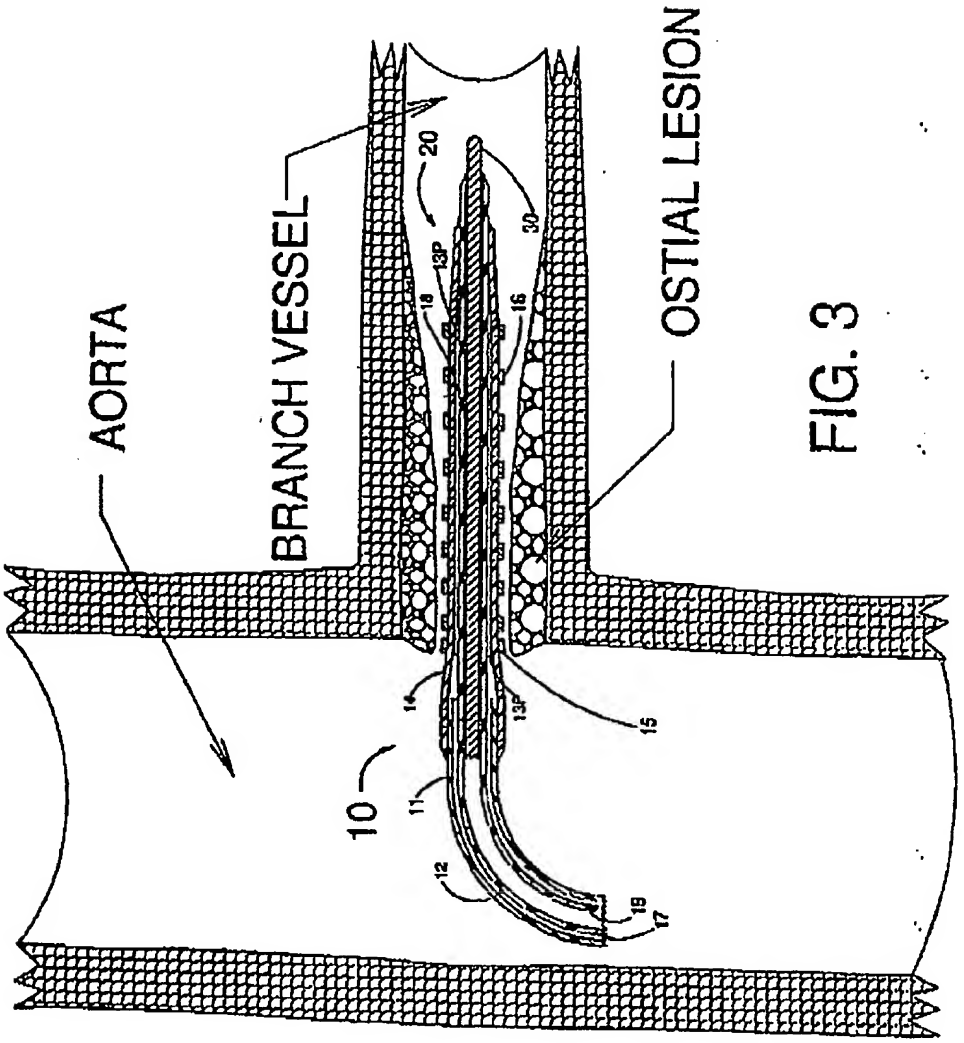
AORTA
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FIG. 3

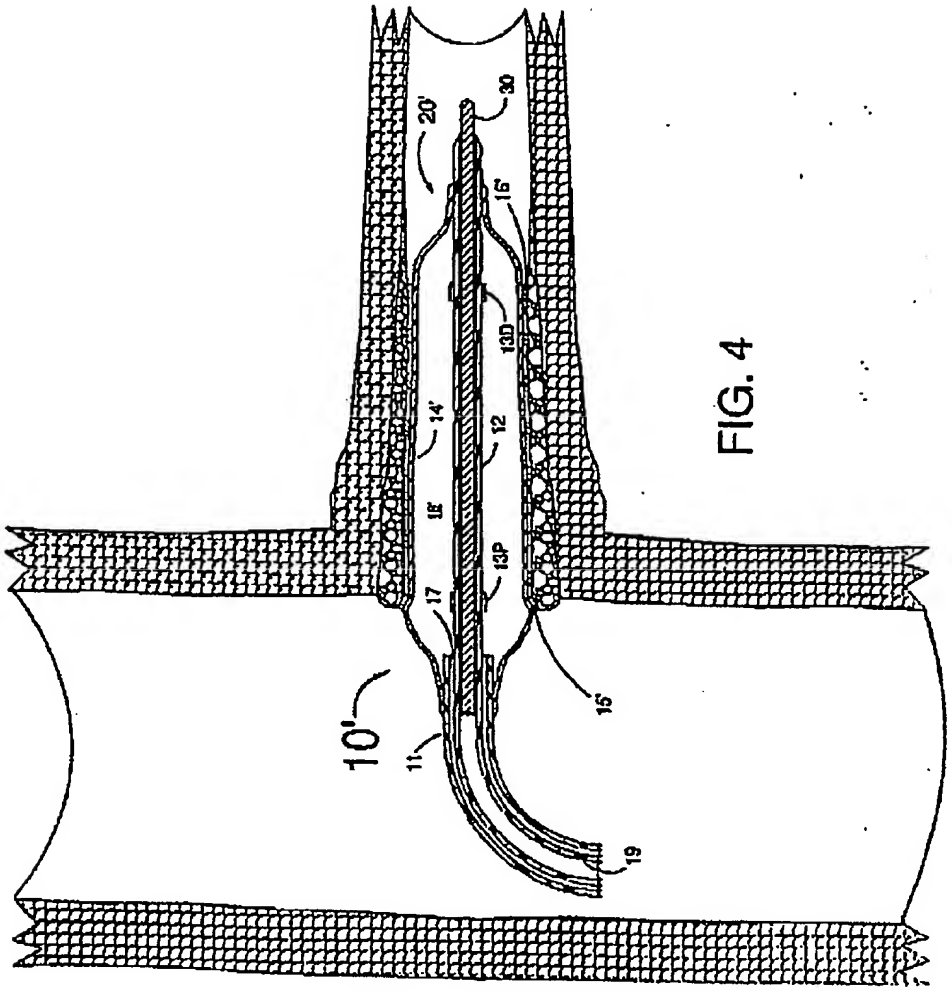

FIG. 4

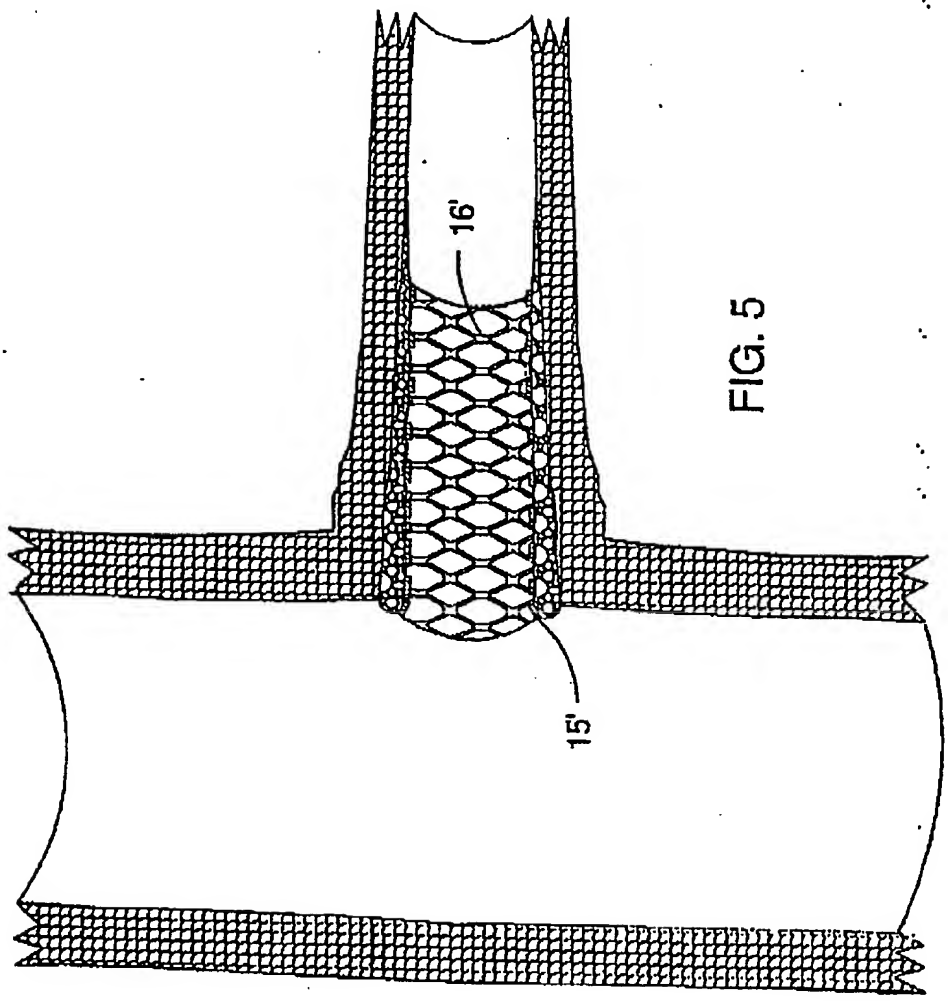

FIG. 5

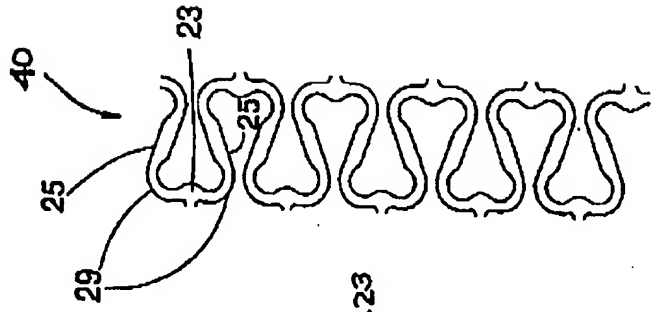

FIG. 7

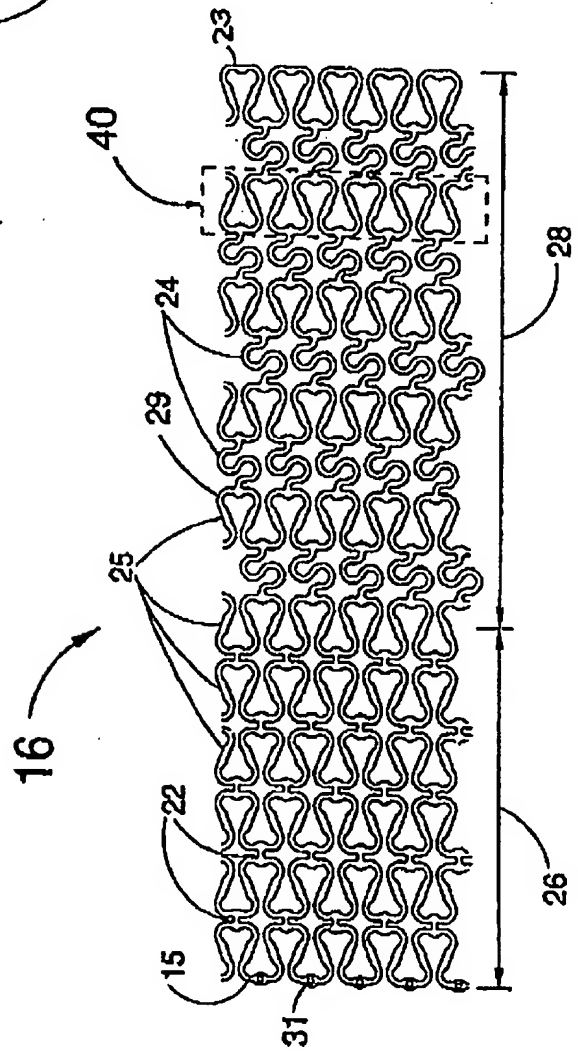

FIG. 6

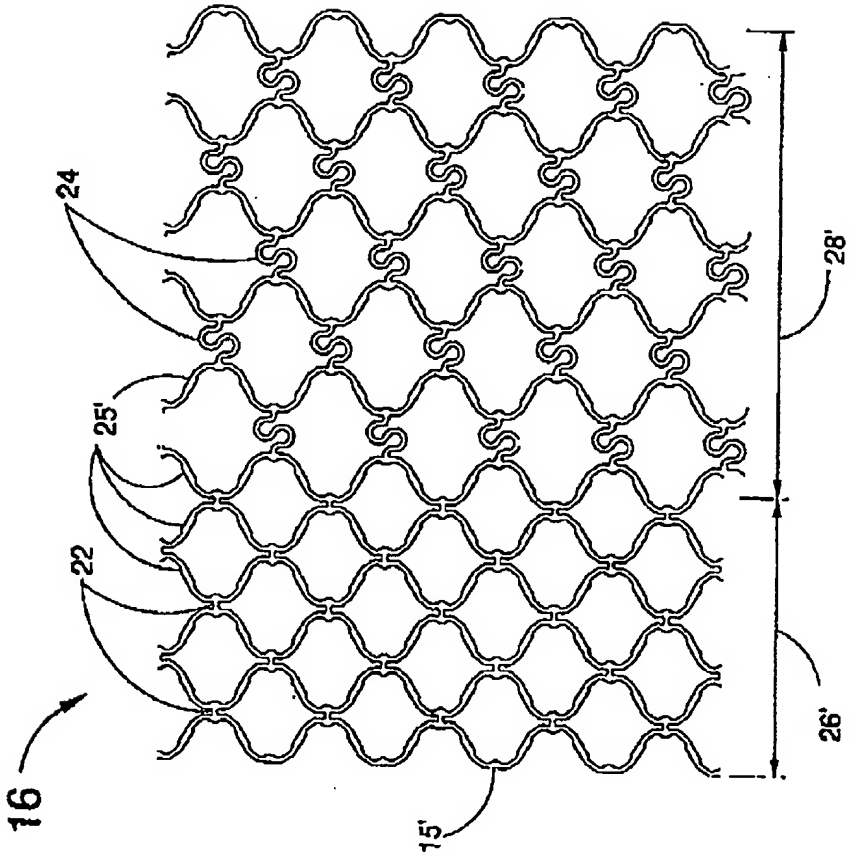

FIG. 8